RULE-MAKING ORDER
PERMANENT RULE ONLY

CR-103P (December 2017)
(Implements RCW 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: March 18, 2025
TIME: 1:13 PM

WSR 25-07-093

Agency: Department of Health – Pharmacy Quality Assurance Commission

Effective date of rule:

Permanent Rules

☒ 31 days after filing.

☐ Other (specify) _____ **(If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)**

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: Dialysate and Dialysis Device Manufacturers and Wholesalers in Home Dialysis Programs. The Pharmacy Quality Assurance Commission (commission) adopted amendments to WAC 246-945-090, 246-945-091, 246-945-092, and 246-945-093 to include manufacturers and wholesalers of dialysis devices and approved legend drugs, including dialysate, in home dialysis program rules under the commission's jurisdiction. The adopted rule is necessary to implement Substitute House Bill (SHB) 1675 (chapter 23, Law of 2022) as well as implement safeguards and quality assurance measures for patients receiving dialysate, dialysis devices, and approved legend drugs from manufacturers and wholesalers.

The commission is adopting the rules as proposed under WSR 24-24-028. This was a supplemental CR-102 which, in response to public comments, differed from the initial proposal under WSR 24-14-140 by proposing to amend WAC 246-945-090 to add the word "may" and list the dialysis devices manufacturers and wholesalers may sell, deliver, possess, or dispense to home dialysis patients, and to amend WACs 246-945-091, 246-945-092, and 246-945-093 to conform to the list of dialysis devices.

Citation of rules affected by this order:

New: None.
Repealed: None.
Amended: WAC 246-945-090, 246-945-091, 246-945-092, and 246-945-093
Suspended: None.

Statutory authority for adoption: RCW 18.64.005, 18.64.257, and 69.41.032

Other authority: None

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 24-24-028 on November 22, 2024.
There were no changes made to the rules as proposed under WSR 24-24-028.

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name: Julia Katz
Address: PO Box 47852, Olympia, WA 98504-7852
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Other:

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	0	Amended	0	Repealed	0
Federal rules or standards:	New	0	Amended	0	Repealed	0
Recently enacted state statutes:	New	0	Amended	4	Repealed	0

The number of sections adopted at the request of a nongovernmental entity:

	New	0	Amended	0	Repealed	0

The number of sections adopted on the agency's own initiative:

	New	0	Amended	0	Repealed	0

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New	0	Amended	0	Repealed	0

The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	0	Amended	4	Repealed	0

Date Adopted: March 14, 2025

Name: Hawkins DeFrance, PharmD

Title: Pharmacy Quality Assurance Commission Chair

Signature:

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-090 Home dialysis programs, manufacturers, and wholesalers—Legend drugs and dialysis devices. Pursuant to RCW 18.64.257 and 69.41.032, a medicare-approved dialysis center ((~~or~~)), a facility operating a medicare-approved home dialysis program ((~~may~~)), a manufacturer, or a wholesaler may sell, deliver, possess, or dispense directly to its home dialysis patients, in case((~~s~~)) or full shelf ((~~package~~)) lots, and if prescribed by a ((~~physician~~)) practitioner, the following:

(1) Legend drugs:

((~~(1)~~)) (a) Sterile heparin, 1000 u/mL, in vials;

((~~(2)~~)) (b) Sterile potassium chloride, 2 mEq/mL, for injection;

((~~(3)~~)) (c) Commercially available dialysate; and

((~~(4)~~)) (d) Sterile sodium chloride, 0.9%, for injection in containers of not less than 150 mL.

(2) Dialysis devices:

(a) Class II medical devices that are manufactured and marketed in compliance with the Federal Food, Drug, and Cosmetic Act and indicated for acute and chronic dialysis therapy in the home; and

(b) Related supplies and accessories of the dialysis device.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-091 Home dialysis programs, manufacturers, and wholesalers—Pharmacist consultant. ((~~Home dialysis programs involved in the distribution of legend drugs as~~)) A medicare-approved dialysis center, a facility operating a medicare-approved home dialysis program, a manufacturer, or a wholesaler who sells, delivers, possesses, or dispenses dialysis devices and legend drugs directly to its home dialysis patients permitted by RCW 18.64.257 and 69.41.032((~~,~~)) shall have an agreement with a pharmacist which provides for consultation as necessary. This agreement shall include advice on the drug ((~~distribution~~)) and device shipment and delivery process to home dialysis patients and on the location used for storage and ((~~distribution~~)) shipment of the authorized drugs and devices, which shall be reasonably separated from other activities and shall be secure.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-092 Home dialysis programs, manufacturers, and wholesalers—Records. (1) A medicare-approved dialysis center, a facility operating a medicare-approved home dialysis program, a manufacturer, or a wholesaler who sells, delivers, possesses, or dispenses dialysis devices and legend drugs directly to its home dialysis patients permitted by RCW 18.64.257 and 69.41.032 shall attach a record

of shipment ((~~shall be attached~~)) to the ((~~prescriber's~~)) practitioner's order ((~~and~~)). The record of shipment shall include:

(a) The name of the patient;

(b) Strengths and quantities of drugs, if applicable;

(c) Device name, if applicable;

(d) The name of the drug manufacturer((~~s' names~~)), if applicable;

((~~(d)~~)) (e) The name of the device manufacturer, if applicable;

(f) Date of shipment;

((~~(e)~~)) (g) Names of persons who selected, assembled and packaged for shipment; and

((~~(f)~~)) (h) The name of the pharmacist or designated individual responsible for the ((~~distribution~~)) shipment.

(2) Prescription records, and drug ((~~distribution~~)) and device shipment records shall be maintained in accordance with WAC 246-945-020.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-093 Home dialysis programs, manufacturers, and wholesalers—Quality assurance. ((~~Home dialysis programs involved in the distribution of legend drugs as~~)) A medicare-approved dialysis center, a facility operating a medicare-approved home dialysis program, a manufacturer, or a wholesaler who sells, delivers, possesses, or dispenses dialysis devices and legend drugs directly to its home dialysis patients permitted by RCW 18.64.257 and 69.41.032((~~,~~)) shall develop a quality assurance program for drug ((~~distribution~~)) and device shipment and delivery, and shall maintain records of drug ((~~distribution~~)) and device shipment and delivery errors and other problems, including loss due to damage or theft.